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13. ABSTRACT (Maximum 200 Words)

Background. Restless Legs Syndrome (RLS) is a commonly under diagnosed organic cause of insomnia. Prevalence ranges from 4% to 16%. Thirty-five percent of US adults report insomnia annually. There is evidence that insomnia leads to psychic distress which impacts health care utilization. **Purpose.** To examine a proposed model which links RLS to insomnia, and insomnia to physic distress and increased utilization. **Scope.** To estimate the prevalence of RLS, insomnia, mood disorders, and substance abuse; quantify the proportion of mood disorders and substance abuse which are attributable to RLS and insomnia; document the diagnosis of RLS and insomnia; and estimate the association of RLS and insomnia to health care utilization and health related quality of life. **Methods.** A cross-sectional survey of a representative sample of Ohio VA clients using telephone interviews and data extracted from medical records. One year follow-up of health care utilization using postal questionnaire and medical records. **Results.** 20% of males and 32% of females reported RLS. 14% of males and 26% of females reported insomnia. 7% of both genders reported severe daytime sleepiness. 3% of those with RLS; 15% of those with insomnia; and 27% of those with severe daytime sleepiness had a diagnosis in the VA medical record. For insomnia, the risk % attributable to RLS was 22%***; to obesity was 27%,** and to female gender was 11%.** For daytime sleepiness, the AR% to insomnia was 27%***; to RLS was 7%**; to male gender was 12%; and to obesity was 12%. *p<.05;**p<.01;***p<.001

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TABLE OF CONTENTS

INTRODUCTION

Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest and when initiating sleep. The sufferer experiences an uncontrollable urge to move in order to relieve symptoms. RLS interferes with the ability to fall asleep or to maintain sleep. The resulting sleep deprivation can interfere with family life, social activities, and job performance. (1) We hypothesize that RLS has a high prevalence in the veteran community and is under diagnosed. We also hypothesize that undiagnosed and untreated RLS is associated with an unknown, but measurable proportion of the insomnia in any population. An association between insomnia and mood and anxiety disorders is well documented, as is the association between these mental health disorders and increased health care utilization. (2;3) In this research, we therefore propose an underlying model in which RLS contributes to insomnia; and insomnia contributes to diminished mental health status. Diminished mental health status in turn may lead to increased health care utilization.

The current research is a study of the prevalence and outcomes of RLS among patients of the Veterans Administration health care system in northern Ohio. The specific goals of the research are the following:

- To estimate the prevalence of Restless Legs Syndrome and insomnia;
- To determine in the VA population the proportion of insomnia that is attributable to RLS;
- To estimate in the VA population the strength of the association of insomnia and RLS with depression, anxiety, and substance abuse adjusting for comorbid health conditions;
- To estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions;
- To document the current level of diagnosis of insomnia and RLS in the VA population;
- To document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions;
- To assess the validity of the questionnaire instrument using interview by a trained clinician as the gold standard.

BODY OF REPORT

STATEMENT OF WORK

The following is the revised statement of work which was submitted on December 18, 2002 and approved by email on February 6, 2003. In April, 2004, Task 6 was added to the project. Tasks which were planned for Year 2 or which occurred in Year 2 of the project are indicated in bold type. The report of our accomplishments with regard to these items follows.

Task 1: Estimate the prevalence of Restless Legs Syndrome, insomnia, mood and anxiety disorders, and substance abuse in persons who have scheduled primary care appointments at a Veterans Administration Community Based Outpatient Clinic (CBOC) in northeast Ohio. Document the current level of diagnosis of insomnia and RLS in the VA population.

a) Hire and train study personnel (Months 1-2)
b) Recruit 1914 study members at CBOC's (Months 3-8)
c) Conduct computer assisted telephone interviews with 1914 Veterans Administration clients. (Months 4-10)
d) Extract problem lists and time 1 utilization data from 1914 electronic medical records. (Months 6-12)
e) Data cleaning and analysis (Months 13-21)
f) Manuscript preparation (Months 20-24)

Task 2: Estimate in the northern Ohio VA population the strength of the association of RLS with insomnia after adjusting for comorbid health conditions. Determine the proportion of insomnia that is attributable to RLS. Estimate in the VA population the strength of the association of insomnia with depression, anxiety, and substance abuse adjusting for comorbid health conditions. Determine the proportion of psychic distress that is attributable to insomnia. Estimate in the VA population strength of the association of insomnia and RLS with health related quality of life adjusting for comorbid conditions.

a) Data analysis (Months 22–30)
b) Manuscript preparation (Months 30-36)

Task 3: Document the level of health care utilization at baseline interview and at one year follow-up associated with insomnia and RLS adjusting for comorbid health conditions.

a) Conduct interviews by mail with 1914 VA clients to determine health care utilization one year after baseline interview. (Months 16-23)
b) Extract time 2 utilization data from 1914 electronic medical records (Months 16 – 23)
c) Data entry, cleaning, and analysis (Months 18 - 30)
d) Manuscript preparation (Months 30 - 36)

*Task 4: A*ssess the validity of the RLS questionnaire using interview by a trained clinician as the gold standard.

a) Recruit study members who are patients at the Akron CBOC and conduct clinical assessment (Months 7 - 18)
b) Analyze data (Months 19 - 20)
c) Manuscript preparation (Months 21 - 24)

Task 5: Assess the external validity of the study sample with respect to the population of VA patients who have had a visit in the past year.

a) Extract population data from electronic patient record system (Months 13-14)
b) Data analysis (Months 15-16)
c) Manuscript preparation is part of *Task 1*.

Task 6: Conduct a pilot study of an aerobic exercise intervention to improve sleep quality among RLS patients by moderating their RLS symptoms.

a) Identify RLS cases, confirm diagnosis and recruit up to 30 study members. Hire and train staff. (Months 25 – 27)
b) Compliance trial. (Month 28)
c) Conduct 3 month crossover study. 3 month intervention and 3 month control condition. (Month 29-34)
d) Analyze data and prepare report. (Month 35-36)

ACCOMPLISHMENTS IN YEAR 2 OF THE RESEARCH.

This year has been devoted to completing data collection, and to data cleaning and preliminary data analysis.

Task 1: Prevalence estimates

Task 1.a Hire and train study personnel.

Task 1.b **Recruit 1914 study members at Community Based Outpatient Clinics.**

Task 1.c **Conduct computer assisted telephone interviews with 1914 Veterans Administration clients.**

Tasks 1 a –c are now completed. Study member recruiting and interviewing ended in August, 2004. 1761 veterans were recruited and interviewed for the research. An additional 351 veterans were recruited and completed the consent procedure but either declined to participate when later contacted for the telephone interview or could not be reached by telephone. Table 1 shows the age and gender distribution of these study members along with the originally planned sample size in each age/ gender group.

As can be seen from Table 1, our recruiting efforts were successful in 6 of 9 age groups. We were unsuccessful in recruiting our planned numbers among men age 40 and younger, and women over age 50. When it became apparent to us that the final sample size would be reduced, we made a decision to over sample in some of the more available age/gender groups in order to retain overall statistical power.

	Age Group	Original Sample Size	Persons Recruited	Completed Interviews
Men	18-30	115	34	26
	31-40	177	82	59
	41-50	177	247	184
	51-60	236	345	282
	61-70	236	305	252
	71-80	236	350	298
	81 +	290	360	311
Women	18-50	157	221	185
	51+	290	175	164
Total		1914	2119	1761

Table 1. Planned and final sample size

Task 1.d Extract problem lists and time 1 utilization data from 1914 electronic medical records.

This Task is complete. The following information was extracted from each participant's medical record located in Computerized Patient Record System (CPRS). CPRS is a computer application of the Veterans Health Information Systems and Technology Architecture (VISTA). Patients were matched with their medical information using the patient's birth date and VA identification number (first letter of last name followed by last 4 digits of social security number).

Problem list.
Problems active at the time of the interview (under the Problems List folder)
Description of problems
ICD-9 codes
Onset dates
Last updated dates
Location (clinic, department, physician or medical team)

Health care utilization
Prescription drugs.
Medications active at the time of the interview (under the Outpatient Rx Profile folder)
Drug class
Date of prescription
Quantity
Number of refills
Status of prescription (active, suspended, discontinued, or expired)

Medications prescribed in a window from six months prior to the interview date to six months after the interview were identified. We were concerned that if we used only the prescriptions one month prior to the interview date that we would miss active medications taken infrequently. This information in conjunction with the quantity prescribed allows us to pick up infrequent, but current prescriptions.

Clinic visits
Clinic visits completed in the month prior to the interview (under the Past Clinic Visits folder)
Type of appointment: lab, radiology, primary care, mental health, physical therapy, optometry, podiatry, etc.
Date of appointment

Hospital admissions
Admissions to VA facility in the month prior to the interview (under Admissions folder)
Principle diagnosis
Date of admission
Date of discharge
Length of stay

Surgical procedures
Procedures and surgeries in the month prior to the interview (under ICD Procedures and ICD Surgeries folders)
ICD code
Date of procedure or surgery
Inpatient or outpatient

Laboratory
Laboratory tests (under the Laboratory & Lab orders folders)
Lab tests within the month prior to the interview
Date of tests
Test result

Radiology
Radiology visits (under radiology folder)
Imaging reports within the month prior to the interview
Type of imaging procedure
Date of test

Diagnosis of RLS and insomnia

We searched inpatient and outpatient medical record data for ICD-9 codes associated with insomnia (307.40-307.49 Specific disorders of sleep of non-organic origin and 780.50-780.59 Sleep disturbances) and RLS (333.99). Because drugs for Parkinson's Disease are first line treatment for RLS, we also searched medication records to see if some patients were given Parkinson's Medications (CN500) but did not have a Parkinson's diagnosis. This approach identified four patients who may have had RLS although RLS was not listed as a diagnosis. Two people were diagnosed with psychogenic pain, one with a sleep disorder NOS, and one with skin sensation disturbance.

Task 1.e Data cleaning and analysis (Months 13-21)

Data cleaning is complete with the exception of the Composite International Diagnostic Index (CIDI). The authors of the CIDI did not provide algorithms for handling missing data. We are currently determining the best approach to that problem. All currently cleaned data has been converted to SAS files preparatory to analysis.

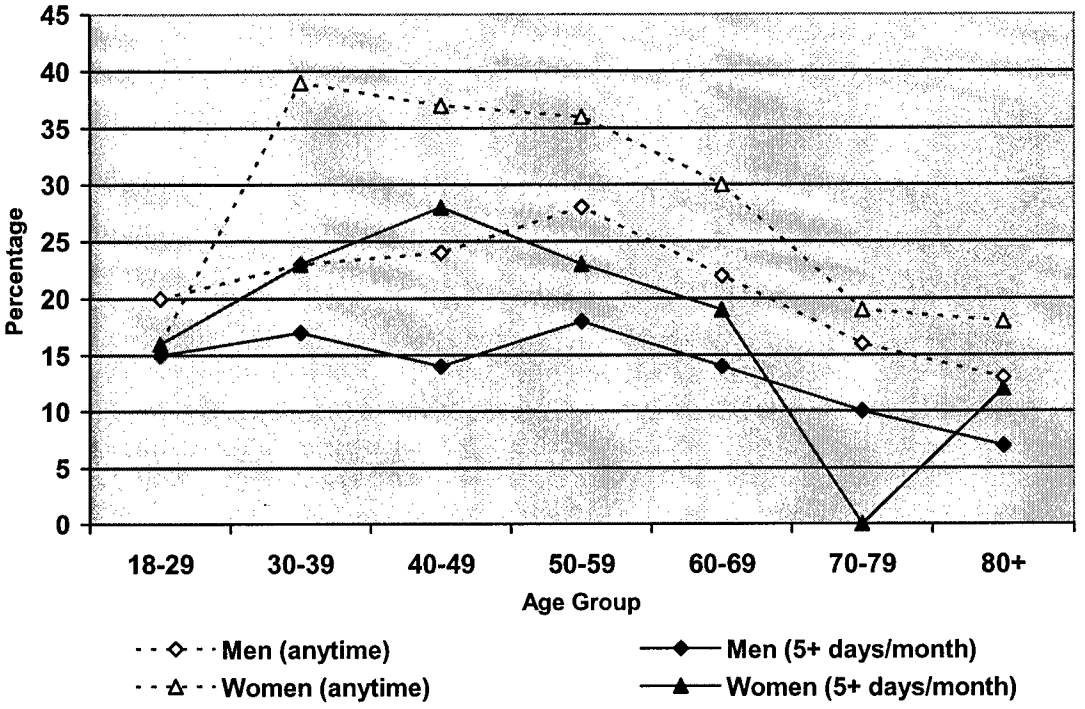
Task 1.f Manuscript preparation (Months 20-24)

Manuscript preparation is underway. Appendix A contains preliminary data tables. Table A.1 shows the descriptive characteristics of the study members. Eighty percent of the sample are men. Most are White/Caucasian (88%) although 8% are African American and 3% are Native American. Almost half (46%) of the sample have at least some college education. An alarming 80% of the sample are overweight or obese and 22% are currently smokers.

Veterans who receive primary care from the VAMC report a high prevalence of symptoms which meet the ILRSSG criteria for a diagnosis of RLS.(4) The overall prevalence of RLS among men is 20% and among women is 32%. Thirteen percent of men and 21% of women report frequent symptoms.

Figure 1 shows the prevalence of RLS by age and gender. Among women, prevalence peaks between the ages of 30 and 50; among men, prevalence peaks between ages 50 and 60. Among younger women, nearly 40% of respondents report occasional symptoms that meet the IRLSSG criteria.

Figure 1. Prevalence of RLS



The prevalence of insomnia and daytime sleepiness are similarly high. Overall, 13% of study members reported moderate insomnia and 3% reported severe insomnia. Eighteen percent of respondents report moderate daytime sleepiness and 7% report severe day time sleepiness.

Figures 2 and 3 show these outcomes stratified by age and gender. While women report higher rates of RLS and insomnia, men report higher rates of excessive daytime sleepiness, especially severe sleepiness. Women age 30 to 50 also report the highest rates of insomnia. Among men, peak levels of insomnia occur in ages 40 to 60. Younger women and middle aged men report the highest levels of daytime sleepiness.

The data from which Figures 1 to 3 were prepared can be found in Appendix A, Table A.2. Table A.2 also shows the 95% confidence intervals around these prevalence estimates.

Figure 2. Prevalence of Insomnia

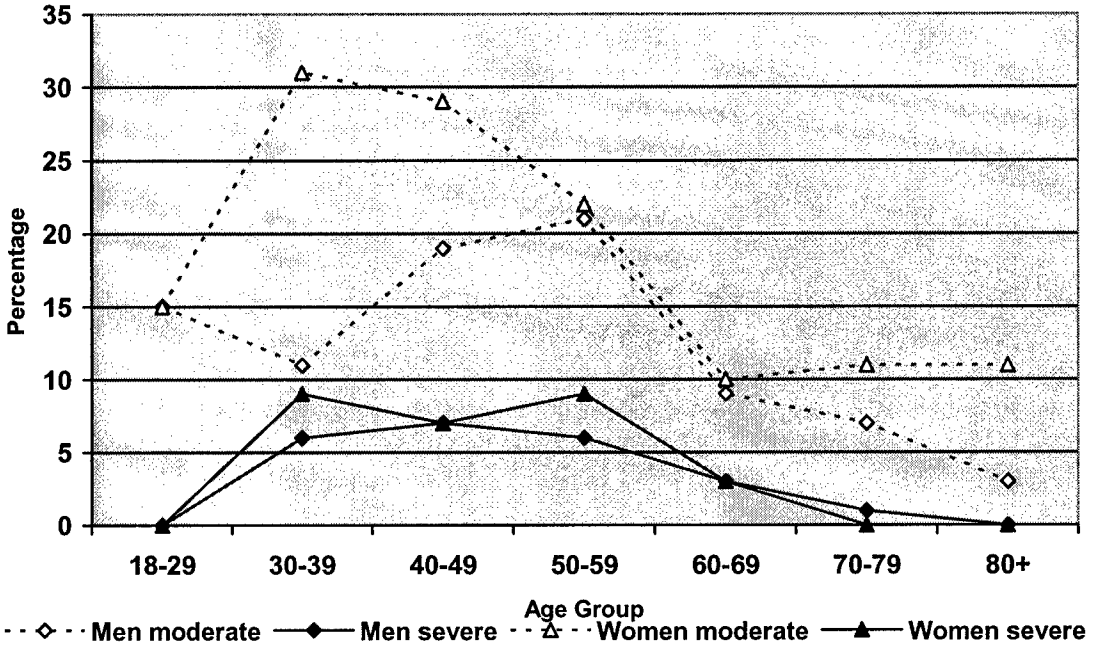
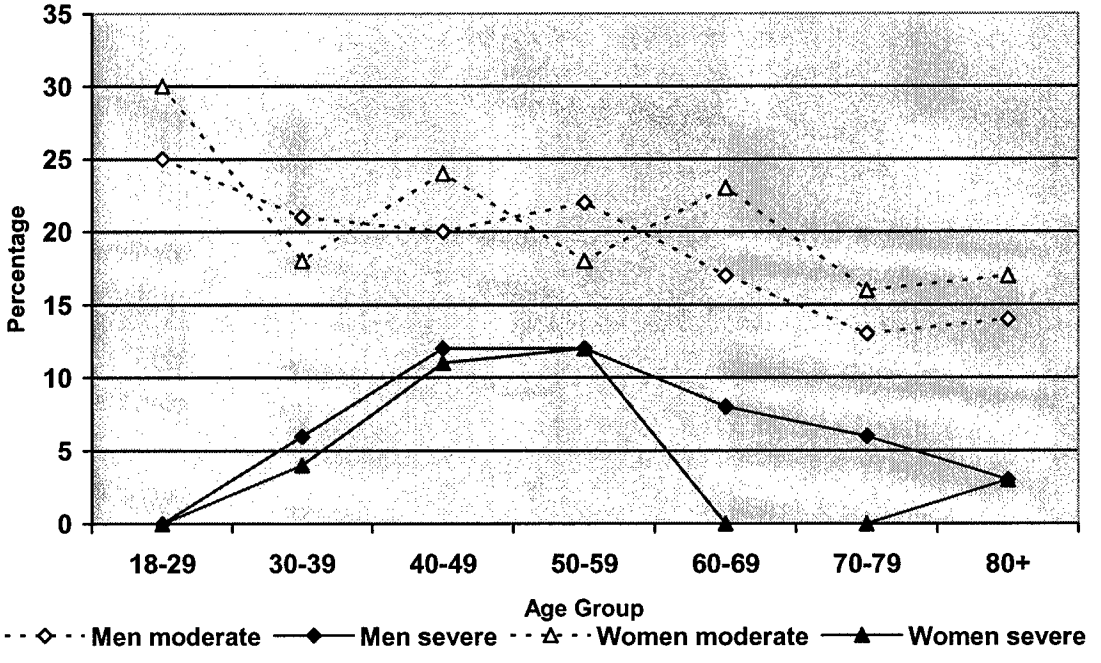


Figure 3. Prevalence of Daytime Sleepiness



In spite of the high prevalence of RLS, insomnia, and excessive daytime sleepiness found by this survey, the level of diagnosis of these conditions found in the VAMC medical records of the study members is low. Three percent of persons who meet the criteria for RLS and 4% of those who report frequent symptoms had an RLS diagnosis anywhere in their medical record. Twenty percent of respondent who reported moderate or severe insomnia had any sleep diagnosis in their medical record. Twenty-seven percent of respondents who reported severe daytime sleepiness had any sleep diagnosis in their medical record. These data can be found in Tables A.3 through A.5.

Task 2: Attributable risk estimation.

Task 2.a Data Analysis.

Data analysis is underway. An abstract which has been accepted for presentation at the Associated Professional Sleep Societies meeting in Denver in June, 2005 (see Appendix B) presents some attributable risk information.

The proportion of insomnia which can be attributed to RLS, gender, age, BMI, alcohol dependence and smoking is shown in Table A.6. This table also shows the proportion of excessive daytime sleepiness attributable to these factors and to insomnia. Odds ratios were calculated using a logistic model with either insomnia or daytime sleepiness as the outcome variable and all other variables are simultaneously included in the model. The prevalence of each risk factor was then used in conjunction with the Odds Ratio to estimate the attributable risk.

For insomnia, factors of greatest importance are RLS (AR% = 22%), age 50-59 (AR% = 49%), and BMI over 29 (AR% = 27%). For daytime sleepiness, factors of greatest importance are insomnia (AR% = 27%), age 50-59 (AR% = 14%), and BMI > 29 (AR% = 12%). About 7% of excessive daytime sleepiness in this sample can be attributed to RLS.

These attributable risk percent estimates do not incorporate adjustment for case-mix. The estimates may change as we conduct analysis which incorporates these adjustments. A discussion of our approach to case-mix adjustment follows.

Three case-mix adjustment methods with available software were researched: Johns-Hopkins ACG Case-Mix System, DxCG Software (DxCG, Inc.), and the Medicare Principal Inpatient Cost Group (PIP-DCG) Model. The input data for each patient that are required by all three methods are essentially the same: a patient identification code, gender, age (or DOB), and ICD-9 codes. All three methods then take this information and create various levels of patient groupings based diagnosis, which are then input, along with age and gender, into regression models to predict health care costs at the patient level.

Based on this research, the Johns-Hopkins ACG Case-Mix System (Version 6.0) was selected and a two-year research license was purchased. This software produces two levels of patient groups: diagnosis clusters called Aggregated Diagnostic Groups (ADG) and Adjusted Clinical Groups (ACG).

Every ICD-9-CM code given to a patient is placed into one of 32 ADGs (Previous versions of the software employed 36 ADGs.) Patients with multiple diagnoses can be assigned to more than one ADG. Based on the ADGs assigned and age and gender, the ACG System uses a branching algorithm to place patients into one of 93 (depending on system options set) discrete

ACGs. Each patient belongs to only one ACG. Individuals within a given ACG have experienced a similar pattern of morbidity and resource consumption.

The data required for the case-mix adjustment have been obtained from the participants' problem lists (see Task 1.d). These data are being restructured for use with the ACG Case-Mix software and the software is being configured for this study.

The primary plan for case-mix adjustment in this research is based on indicator variables for each of the ADGs (1 = present, 0 = absent), which will be included as predictors in logistic regression models. Version 6 of the ACG Case-Mix software produces two additional classifications that may be useful for case-mix adjustment: Resource Utilization Bands (RUB), which are six cost-based ACG groupings and revised Expanded Diagnosis Clusters (EDC), which are morbidity-based groupings. These will be explored for direct case-mix adjustment and as input to the development of case-mix scores (CMS). CMS are composite case-mix variables, which will be constructed using principal components analysis. Fewer CMS variables can contain much of the information in the original case-mix variables (e.g. ADG indicators, RUB, EDC).(5)

Task 3: Time 2 utilization data.

Task 3.a Conduct interviews by mail with 1914 VA clients to determine health care utilization one year after baseline interview.

Work on this task began in June, 2004 which was the one year anniversary of the start of interviewing. To date, 849 follow-up questionnaires have been mailed to study members and 607 have been returned. This is a 71% response rate.

Task 3.b Extract time 2 utilization data from 1914 electronic medical records

Time 2 medical record data can be obtained after the one year anniversary of the study member's interview. We have Time 2 medical record data for the first 458 patients (i.e., those interviewed before Oct. 1st, 2003). Additional batch medical records data extractions will be done later this year.

Task 3.c Data entry, cleaning, and analysis

Data entry and cleaning occur as data arrives in our office. Data analysis must wait for the completion of data collection.

Task 4. The Validation Substudy

Task 4.a Recruit study members who are patients at the Akron CBOC and conduct clinical assessment.

Recruiting study members began in November, 2004, but was then immediately halted pending IRB approval of a change in the study protocol. Patient recruiting began again in January, 2005. Fifteen study members have been recruited and 4 have been interviewed. Our goal for

this substudy is 82 study members. Dr. Panzner is able to schedule 2 patient interviews a week. Thus 40 weeks may be required to complete this data collection. A second clinician has been recruited to assist with the clinical interviews. His level of participation is still under negotiation.

Task 4.b Analyze data
Task 4.c Manuscript preparation

These two activities are pending the completion of data collection.

Task 5. Assess external validity of study sample

Task 5.a **Extract population data from electronic patient record system (Months 13-14)**

Our plan for assessing the external validity of the study sample, consists of comparing utilization data from our sample to utilization data pertaining to the appropriate sampling frame. The study sample consists of a Community Based Outpatient Center, age, and gender stratified sample of patients who were seen for a primary care visit. Thus, the population consists of the CBOC, age and gender stratified Veterans who have had a primary care visit in the past year. Comparison of number of office visits and number of prescriptions is planned.

Therefore, a request has been made to the Cleveland VA Primary Care administration for the following information. Age/ gender / CBOC stratified mean number of office visits and number of prescriptions among all registered patients who had a primary care visit in the past year. The computer programmer has given us an expected completion date of the end of March, 2005 for that request.

Task 5.b **Data analysis (Months 15-16)**

Pending available data.

Task 5.c **Manuscript preparation is part of *Task 1.***

KEY RESEARCH ACCOMPLISHMENTS

- Recruited and interviewed 1761 study members.
- Extracted time 1 medical record data for 1761 study members.
- Cleaned time 1 datasets and prepared working data files.
- Calculated estimates of the prevalence of RLS, insomnia, and daytime sleepiness.
- Calculated preliminary estimates of Attributable Risk % of factors contributing to insomnia and daytime sleepiness.
- Mailed 849 follow-up questionnaires; received 607 completed responses.
- Extracted time 2 medical record data on the first 458 study members.
- Recruited 15 and interviewed 4 study members for the Validation Substudy.

REPORTABLE OUTCOMES

Abstract accepted for poster presentation at the meeting of the Associated Professional Sleep Societies (APSS) meeting, Denver, June, 2005 and to be published in a special issue of the Journal, *Sleep.* (Abstracts are included in Appendix B).

Abstract submitted for presentation at the annual meeting of the Society for Epidemiologic Research, Toronto, Ontario, Canada, June, 2005.

CONCLUSIONS

Restless Legs Syndrome, Insomnia, and Daytime Sleepiness are common complaints among primary care patients seen at VA outpatient clinics. RLS, obesity, alcohol dependence, and gender, are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Because of the high prevalence of obesity, RLS, and insomnia in this patient population, the Attributable Risk associated with these factors is substantial. Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS by their physicians. These conclusions are based on preliminary analysis of the data.

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APPENDICES

A. Detailed tables

B. Abstract accepted for presentation at scientific meetings.

APPENDIX A – DETAILED TABLES

Table A.1: Demographic Characteristics of Study Sample

Table A.2. Prevalence of RLS, Insomnia, and Daytime Sleepiness by Gender and Age

Table A.3. Diagnosis of RLS at the VA (either on the current problems list or diagnosed in the past but no longer on problems list)

Table A.4. Persons ever diagnosed with a sleep problem at the VA stratified by Insomnia Severity Scale scores

Table A.5. Persons ever diagnosed with a sleep problem at the VA stratified by Epworth Sleepiness Scale scores

Table A.6. Proportion of insomnia and excessive daytime sleepiness attributable to RLS and other risk factors.

Table A.1: Demographic Characteristics of Study Sample

	Women	Men	All
	% (n)	% (n)	% (n)
Age 20-29	7.7 (27)	1.4 (20)	2.7 (47)
Age 30-39	12.9 (45)	3.8 (53)	5.6 (98)
Age 40-49	30.1 (105)	11.8 (167)	15.5 (272)
Age 50-59	22.4 (78)	20.3 (287)	20.7 (365)
Age 60-69	11.2 (39)	17.9 (252)	16.5 (291)
Age 70-79	5.4 (19)	20.0 (283)	17.2 (302)
Age 80+	10.3 (36)	24.8 (350)	21.9 (386)
Total	100 (349)	100 (1412)	100 (1761)
Hispanic	2.6 (9)	2.3 (32)	2.4 (41)
White	74.3 (252)	91.4 (1270)	88.1 (1522)
African American	17.7 (60)	5.6 (78)	8.0 (138)
Native American	4.7 (16)	2.5 (35)	3.0 (51)
Asian American	1.2 (4)	.2 (3)	.4 (7)
Other	2.1 (7)	.2 (3)	.6 (10)
Total	100 (339)	100 (1389)	100 (1728)
BMI < 25	26.3 (89)	17.9 (250)	19.6 (339)
BMI 25-29	29.8 (101)	41.6 (580)	39.3 (681)
BMI > 29	44.0 (149)	40.5 (564)	41.14 (713)
Total	100 (339)	100 (1394)	100 (1733)
Grade School	0 (0)	3.3 (46)	2.6 (46)
Some High School	2.9 (10)	12.9 (180)	10.9 (190)
High School graduate	31.8 (110)	43.2 (604)	40.9 (714)
Some College	43.4 (150)	26.9 (376)	30.2 (526)
College graduate	18.8 (65)	10.3 (144)	12.0 (209)
Graduate School	3.2 (11)	3.4 (48)	3.4 (59)
Total	100 (346)	100 (1398)	100 (1744)
Currently Smokes	31.4 (109)	19.7 (275)	22.0 (384)

Table A.2. Prevalence of RLS, Insomnia, and Daytime Sleepiness by Gender and Age

	Women	Men	All
RLS			
	Prev. (95% CI), N	Prev. (95% CI), N	Prev. (95% CI), N
Age 20-29	.16 (CI: .06, .35), 25	.20 (CI: .08, .42), 20	.18 (CI: .09, .32), 45
Age 30-39	.39 (CI: .24, .53), 44	.23 (CI: .12, .35), 52	.30 (CI: .21, .39), 96
Age 40-49	.37 (CI: .28, .46),103	.24 (CI: .18, .31),166	.29 (CI: .24, .34), 269
Age 50-59	.36 (CI: .26, .47), 74	.28 (CI: .23, .33),278	.30 (CI: .25, .35), 352
Age 60-69	.30 (CI: .15, .44), 37	.22 (CI: .16, .27),241	.23 (CI: .18, .28), 278
Age 70-79	.19 (CI: .06, .44), 16	.16 (CI: .11, .20),272	.16 (CI: .12, .20), 288
Age 80+	.18 (CI: .08, .35), 33	.13 (CI: .09, .16), 30	.13 (CI: .10, .17), 363
For all ages	.32 (CI: .27, .37),332	.20 (CI: .18, .22),359	.22 (CI: .20, .24), 1691
Severe RLS (Symptoms at least 5 days per month)			
Age 20-29	.16 (CI: .06, .35), 25	.15 (CI: .05, .37), 20	.16 (CI: .07, .29), 45
Age 30-39	.23 (CI: .10, .35), 44	.17 (CI: .09, .30), 52	.20 (CI: .12, .28), 96
Age 40-49	.28 (CI: .19, .37),103	.14 (CI: .09, .20),166	.20 (CI: .15, .24), 269
Age 50-59	.23 (CI: .13, .33), 74	.18 (CI: .14, .23),278	.19 (CI: .15, .23,), 352
Age 60-69	.19 (CI: .09, .35), 37	.14 (CI: .10, .19),241	.15 (CI: .11, .19), 278
Age 70-79	.00 (CI:---), 16	.10 (CI: .07, .14),272	.10 (CI: .06, .13), 288
Age 80+	.12 (CI: .04, .28), 33	.07 (CI: .04, .10), 30	.07 (CI: .05, .10), 363
For all ages	.21 (CI: .17, .26),332	.13 (CI: .11, .14),359	.14 (CI: .13,.16), 1691

Table A.2 Continued

	Women	Men	All
	Prev. (95% CI), N	Prev. (95% CI), N	Prev. (95% CI), N
Moderate Insomnia			
Age 20-29	.15 (CI: .05, .33), 27	.15 (CI: .05, .37), 20	.15 (CI: .07, .28), 47
Age 30-39	.31 (CI: .18, .45), 45	.11 (CI: .05, .23), 53	.20 (CI: .12, .28), 98
Age 40-49	.29 (CI: .20, .37),105	.19 (CI: .13, .25), 67	.23 (CI: .18, .28), 272
Age 50-59	.22 (CI: .13, .31), 78	.21 (CI: .16, .25),287	.21 (CI: .17, .25), 365
Age 60-69	.10 (CI: .04, .24), 39	.09 (CI: .06, .13),252	.09 (CI: .06, .13), 291
Age 70-79	.11 (CI: .02, .33), 19	.07 (CI: .04, .10),283	.07 (CI: .04, .10), 302
Age 80+	.11 (CI: .04, .26), 36	.03 (CI: .02, .05),350	.04 (CI: .02, .06), 386
For all ages	.21 (CI: .17, .26),349	.11 (CI: .09, .13), 1412	.13 (CI: .11, .15), 1761
Severe Insomnia			
Age 20-29	.00, 27	.00, 20	.00, 47
Age 30-39	.09 (CI: .03, .21), 45	.06 (CI: .01, .16), 53	.07 (CI: .03, .14), 98
Age 40-49	.07 (CI: .03, .13),105	.07 (CI: .03, .10),167	.07 (CI: .04, .10), 272
Age 50-59	.09 (CI: .04, .18), 78	.06 (CI: .03, .09),287	.07 (CI: .04, .09), 365
Age 60-69	.03 (CI: .00, .15), 39	.03 (CI: .01, .06),252	.03 (CI: .01, .05), 291
Age 70-79	.00, 19	.01 (CI: .00, .03),283	.01 (CI: .00, .03), 302
Age 80+	.00, 36	.003 (CI: .00, 02), 350	.003 (CI: .00, .02), 386
For all ages	.05 (CI: .03, .08),349	.03 (CI: .02, .04), 1412	.03 (CI: .03, .04), 1761

Table A.2. Continued

	Women	Men	All
	Prev. (95% CI), N	Prev. (95% CI), N	Prev. (95% CI), N
Moderate Daytime Sleepiness			
Age 20-29	.30 (CI: .16, .49), 27	.25 (CI: .11, .47), 20	.28 (CI: .15, .40), 47
Age 30-39	.18 (CI: .09, .32), 45	.21 (CI: .10, .32), 53	.19 (CI: .12, .27), 98
Age 40-49	.24 (CI: .16, .32), 105	.20 (CI: .14, .26),167	.22 (CI: .17, .27), 272
Age 50-59	.18 (CI: .09, .26), 78	.22 (CI: .17, .27),287	.21 (CI: .17, .26), 365
Age 60-69	.23 (CI: .13, .39), 39	.17 (CI: .12, .22),252	.18 (CI: .13, .22), 291
Age 70-79	.16 (CI: .05, .39), 19	.13 (CI: .09, .17),283	.14 (CI: .10, .17), 302
Age 80+	.17 (CI: .08, .32), 36	.14 (CI: .10, .17),349	.14 (CI: .11, .17), 385
For all ages	.21 (CI: .17, .25), 349	.17 (CI: .15, .19), 1411	.18 (CI: .16, .20), 1760
Severe Daytime Sleepiness			
Age 20-29	.00, 27	.00, 20	.00, 47
Age 30-39	.04 (CI: .00, .16), 45	.06 (CI: .01, .16), 53	.05 (CI: .02, .12), 98
Age 40-49	.11 (CI: .05, .16), 105	.12 (CI: .07, .17),167	.11 (CI: .08, .15), 272
Age 50-59	.12 (CI: .06, .21), 78	.12 (CI: .08, .15),287	.12 (CI: .08, .15), 365
Age 60-69	.00, 39	.08 (CI: .05, .12),252	.07 (CI: .04, .10), 291
Age 70-79	.00, 19	.06 (CI: .03, .08),283	.05 (CI: .03, .08), 302
Age 80+	.03 (CI: .00, .16), 36	.03 (CI: .01, .05),349	.03 (CI: .01, .05), 385
For all ages	.07 (CI: .04, .09), 349	.07 (CI: .06, .09), 1411	.07 (CI: .06, .08), 1760

Table A.3. Diagnosis of RLS at the VA (either on the current problems list or diagnosed in the past but no longer on problems list)

	RLS symptoms 5 or more days a month	
Diagnosis at VA	No	Yes
No	1438 (99%),	233 (96%),
Yes	10 (1%),	10 (4%),

	Any RLS symptoms	
Diagnosis at VA	No	Yes
No	1304 (99%),	367 (97%),
Yes	10 (1%),	10 (3%),

Table A.4. Persons ever diagnosed with a sleep problem at the VA stratified by Insomnia Severity Scale scores

	Sleep Study Diagnosis			
Diagnosis of sleep problem by VAMC	No Insomnia	Mild Insomnia	Moderate Insomnia	Severe Insomnia
No	976 (95%)	387 (88%)	180 (79%)	52 (85%)
Yes	56 (5%)	52 (12%)	49 (21%)	9 (15%)

Table A.5. Persons ever diagnosed with a sleep problem at the VA stratified by Epworth Sleepiness Scale scores

	Sleep Study Diagnosis		
Diagnosis of sleep problem by VAMC	No or little daytime sleepiness	Moderate daytime sleepiness	Severe daytime sleepiness
No	1227 (93%)	274 (87%)	93 (73%)
Yes	90 (7%)	49 (13%)	9 (27%)

Table A.6. Proportion of insomnia and excessive daytime sleepiness attributable to RLS and other risk factors.

	Outcome: Insomnia		Outcome: Daytime Sleepiness	
	Odds Ratios	Attributable Risk %	Odds Ratios	Attributable Risk %
Risk factor				
Insomnia			3.17***	26.71
Frequent RLS case	2.90***	21.53	1.55**	7.30
Gender	1.61**(female),	10.67	1.17 (male),	11.99
Age 20-29	2.18	2.97	1.81	2.06
Age 30-39	4.38***	16.09	1.12	.68
Age 40-49	5.05***	38.93	1.74*	10.41
Age 50-59	5.66***	49.24	1.76**	13.61
Age 60-69	2.42**	19.02	1.37	5.81
Age 70-79	1.78	11.81	1.00	-0.03
Age 80+	Ref		Ref	
BMI < 25	Ref		Ref	
BMI 25-29	1.07	2.75	.97	-1.39
BMI > 29	1.88**	26.65	1.34	12.41
Alcohol Dependence	2.31**	4.10	.87	-.44
Currently Smokes	1.29	6.05	.91	-2.01

* p<.05
** p< .01
***p<.001

APPENDIX B – MEETING ABSTRACTS

Abstracts submitted for presentation in 2005

Accepted for presentation at the meeting of the Associated Professional Sleep Societies, Denver, June, 2005.

Title: Insomnia and Daytime Sleepiness: Risk Attributable to RLS, BMI, Smoking, and Alcohol in a VA Outpatient Population

Authors: Baughman KB[1], Bourguet CC[2], Ober SK[1], Steiner RP[3], Shapiro HD[4]

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Introduction: Insomnia and daytime sleepiness are common among patients with Restless Legs Syndrome (RLS). The goal of this research was to estimate the prevalence of insomnia and daytime sleepiness and to estimate the contribution of RLS and other behavioral factors to these complaints in primary care patients.

Methods: Telephone interviews were conducted with 1761 patients recruited at 12 VA primary care clinics in Ohio. Measures of RLS, insomnia, daytime sleepiness, alcohol dependence, smoking and BMI were included. Logistic regression was used to obtain odds ratios that were used with risk factor prevalence to estimate attributable risks (AR).

Results: Patients were aged 22 to 92. Eighty percent of the sample were male, 41% had a BMI of 30 or over, and 46% had post high school education. The prevalence of RLS symptoms at least once per week was 21% for women and 13% for men. Moderate or severe insomnia was more common in women (27% compared to 14% for men). Both genders had a 7% prevalence of daytime sleepiness. In predicting insomnia, the attributable risk was 22% ($p<.0001$) for RLS, 27% ($p=.003$) for a BMI of 30 or over, 4% ($p=.007$) for alcohol dependence, and 6% ($p=.12$) for smoking. In predicting daytime sleepiness, the AR for insomnia was 27% ($p<.0001$) and 7% ($p=.006$) for RLS. Obesity, smoking, and alcohol dependence did not have a significant relationship to daytime sleepiness beyond their effects on insomnia. Only 10 of the 243 patients who reported RLS symptoms had been diagnosed with RLS.

Conclusion: RLS, obesity, alcohol dependence, and gender, are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS by their physicians.

Supported by DAMD17-03-1-0082 from the US Army Medical Research and Materiel Command and a grant from Pfizer Pharmaceutical Corporation.

Submitted for presentation at the meeting of the Society for Epidemiologic Research, Toronto, Ontario, Canada, June, 2005

Insomnia and Daytime Sleepiness: Risk Attributable to Restless Legs Syndrome, BMI, Smoking, and Alcohol among VA Outpatients.

*C.C. Bourguet, R.P. Steiner, S.K. Ober, K.R. Baughman, H.D. Shapiro. (N. E. Ohio Universities College of Medicine, Rootstown, OH 44272)

Insomnia and daytime sleepiness are common among patients with Restless Legs Syndrome (RLS). This research was planned to estimate the prevalence of insomnia and daytime sleepiness and to estimate the contribution of RLS and other behavioral factors to these complaints in primary care patients.

Telephone interviews were conducted with 1761 patients recruited at 12 VA primary care clinics in Ohio. Measures of RLS, insomnia, daytime sleepiness, alcohol dependence, smoking and BMI were included. Logistic regression was used to obtain odds ratios that, with risk factor prevalence, estimated attributable risks (AR).

Patients were aged 22 to 92. Eighty percent of the sample were male, 41% had a BMI of 30 or over, and 46% had post high school education. The prevalence of RLS symptoms at least once per week was 21% for women and 13% for men. Moderate or severe insomnia was more common in women (27% compared to 14% for men). Both genders had a 7% prevalence of daytime sleepiness. In predicting insomnia, the attributable risk was 22% ($p<.0001$) for RLS, 27% ($p=.003$) for a BMI of 30 or over, 4% ($p=.007$) for alcohol dependence, and 6% ($p=.12$) for smoking. In predicting daytime sleepiness, the AR for insomnia was 28% ($p<.0001$) and 7% ($p=.006$) for RLS. Obesity, smoking, and alcohol dependence did not have a significant relationship to daytime sleepiness beyond their effects on insomnia. Only 10 of the 243 patients who reported RLS symptoms had received a diagnosis.

RLS, obesity, alcohol dependence, and gender, are significant risk factors for insomnia. Insomnia, in turn, is a significant risk factor for daytime sleepiness. RLS is a significant risk factor for daytime sleepiness, even after controlling for insomnia. Despite the impact of RLS on insomnia and daytime sleepiness, few patients are diagnosed with RLS by their physicians.

Supported by the US Army Medical Research and Materiel Command and Pfizer Pharmaceutical Corporation.

Abstracts presented at scientific meetings in 2003 and 2004 (included in Year 1 report).

Presented at the meeting of the Associated Professional Sleep Societies in Philadelphia, June, 2004.

The Prevalence and Outcomes of Restless Legs Syndrome among Veterans.
Ober SK, Bourguet CC, Baughman KR, Steiner RP, and Shapiro, HD.

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. Sufferers experience an uncontrollable urge to move to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization. **Methods:** Study members were a representative sample of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p<.01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p <.0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS were associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized explanatory model. The final sample (n=1914) will allow precise estimates of RLS prevalence in age strata. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.

Abstract presented at the Peer Reviewed Medical Research Program Military Health Research Forum (Investigators' Meeting), San Juan, Puerto Rico, April, 2004.

THE PREVALENCE AND OUTCOMES OF RESTLESS LEGS SYNDROME AMONG VETERANS. Bourguet CC, Ober SK, Baughman KR, Steiner RP, Shapiro, HD. The Northeastern Ohio Universities College of Medicine.

BACKGROUND/ PURPOSE: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. The sufferer experiences an uncontrollable urge to move in order to relieve these symptoms. RLS interferes with the ability to fall asleep or maintain sleep. Estimates of the prevalence of RLS in community populations ranges from 4% to 17%. A 29% prevalence has been reported in one VA outpatient sample. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care outpatient clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status, and diminished mental health status leads to increased health care utilization. **METHODS:** Study members are a representative sample (final sample size = 1914) of Veterans seen at Community Based Outpatient Clinics affiliated with the Louis B. Stokes Cleveland VA Medical Center in Ohio. A cross-sectional telephone survey is being used to determine the prevalence of RLS and insomnia. Patients are classified as non-RLS cases, probable (3 criteria) or definite (4 criteria) cases. Health measures include the Mental and Physical Composite Scales (MCS and PCS) of the SF12, the WHO's Composite International Diagnostic Index (Short Form), and the problem list from the medical record. Utilization measures will be obtained from the patient and the medical record and include: number of office visits, diagnostic procedures, prescribed medications, hospitalizations, and surgical procedures. Additional utilization data will be collected at one year follow-up. All data analysis includes adjustment for age, gender, Body Mass Index, and physical health status (PCS score). **RESULTS:** Preliminary results from 620 patients are reported here. Forty-five percent of patients who were approached completed an interview. The sample includes 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS is 15.8%, definite RLS is 9.7%, moderate insomnia is 9.9% and severe insomnia is 3.3%. Among women, the prevalence of probable RLS is 19.7%, definite RLS is 14.5%, moderate insomnia is 26.3%, and severe insomnia is 7.9%. The insomnia score of an average patient increases 53% in the presence of 4 RLS symptoms ($p < .001$). In this VA sample, the mean MCS scores is 50.3, similar to the US population mean. The mean PCS score is 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS is significantly lower (41.0, $p<.01$), as is the mean MCS score of persons with moderate insomnia (40.6, $p < .0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappears when insomnia is included in the regression model. Analysis of utilization data obtained from patients finds that neither insomnia nor RLS is associated with physicians visits. RLS but not insomnia is positively associated ($p=.04$) with diagnostic testing. **CONCLUSION:** Preliminary analysis of approximately one third of the planned sample offers support for the hypothesized explanatory model. The final sample will allow precise estimates of RLS prevalence in age strata. Data obtained from medical records will allow improved adjustment for health status and more definitive conclusions about the relationship between sleep disorders and health care utilization.

THE U.S. ARMY MEDICAL RESEARCH MATERIEL COMMAND UNDER DAMD17-03-1-0082 SUPPORTED THIS WORK.

Abstract presentated at the Research and Education Forum of the Ohio Academy of Family Physicians, Columbus, Ohio, April, 2003.

The Prevalence and Outcomes of Restless Legs Syndrome among Patients at VA Primary Care Clinics. Baughman K., Panzner M., Ober S., Bourguet C., Steiner R. Louis Stokes Department of Veterans Affairs Medical Center, Brecksville, OH 44141

Introduction: Restless Legs Syndrome (RLS) is a sensori-motor disorder characterized by unpleasant, abnormal feelings in the legs and occasionally arms which occur at rest or when initiating sleep, and in the evening or at night. RLS interferes with the ability to fall asleep or maintain sleep. The goal of this research is to estimate the prevalence of RLS and insomnia among patients seen at VA primary care clinics. This research investigates an explanatory model in which RLS contributes to insomnia. Insomnia contributes to diminished mental health status and to increased health care utilization. **Methods:** Study members were representative of Veterans seen at primary care clinics affiliated with the Cleveland VA Medical Center. A telephone survey was used to determine the prevalence of RLS and insomnia. Patients were classified as non-RLS cases, probable or definite cases. Health status was measured using the Mental and Physical Composite Scales (MCS and PCS) of the SF12. Utilization information was obtained from the patient and included: number of office visits, diagnostic procedures, hospitalizations, and surgical procedures. All tests of hypothesized relationships were adjusted for age, gender, Body Mass Index, and physical health status (PCS score). **Results:** Preliminary results from 620 patients are reported. Forty-five percent of patients who were approached completed an interview. The sample included 544 men and 76 women, age range 25 to 89 years. Among men, the prevalence of probable RLS was 15.8%, definite RLS was 9.7%, moderate insomnia was 9.9% and severe insomnia was 3.3%. Among women, the prevalence of probable RLS was 19.7%, definite RLS was 14.5%, moderate insomnia was 26.3%, and severe insomnia was 7.9%. The insomnia score of an average patient increased 53% in the presence of definite RLS ($p < .001$). The mean MCS score was 50.3, similar to the US population mean. The mean PCS score was 39.9, one standard deviation below the US mean. The mean MCS score of persons with probable or definite RLS was significantly lower (41.0, $p<.01$), as was the mean MCS score of persons with moderate insomnia (40.6, $p <.0001$) and of persons with severe insomnia (34.7, $p<.0001$). As hypothesized, the association between RLS and the MCS disappeared when insomnia was included in the regression model. Analysis of utilization data obtained from patients found that neither insomnia nor RLS was associated with physicians visits. RLS but not insomnia was positively associated ($p = .04$) with diagnostic testing. **Conclusions:** Preliminary analysis of approximately one third of the planned sample offered support for the hypothesized model in which RLS impacts health outcomes and utilization through insomnia. **Support:** Supported by the US Army Medical Research and Materiel Command under DAMD17-03-1-0082.